

ADARSH GANDHI

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OBJECTIVE

- ✓ To design, conduct and support ADME and PK-PD studies utilizing *in vivo* and *in vitro* approaches for effective translation of preclinical data to clinical settings for CNS drugs

EDUCATION

- ✓ **Doctor of Philosophy**, Pharmaceutics, University of Houston, Houston, TX August 2012
- ✓ **Master of Science**, Pharmaceutical Chemistry, Fairleigh Dickinson University, Madison, NJ May 2007
- ✓ **Bachelor of Pharmacy**, University of Pune, NDMVPs College of Pharmacy, Nasik, India May 2005

RESEARCH EXPERIENCE

- 1. Scientist, Lundbeck Research Inc. USA**, Paramus, NJ October 2013 – Present
 - ✓ Develop high-throughput bioanalytical methods for screening pharmacological tool compounds
 - ✓ Develop a robust high-throughput protein binding assay to support various aspects of CNS drug discovery
- 2. Postdoctoral Fellow, National Institute on Drug Abuse (NIDA)**, Baltimore, MD August 2012 – October 2013
 - ✓ To develop and validate quantitative and qualitative analytical methods for drugs of abuse in various clinical specimens
 - ✓ To characterize metabolism and perform metabolite profiling of novel designer drugs using human hepatocytes and liver microsomes
- 3. Summer Intern, Janssen Research and Development, LLC.**, Raritan, NJ June 2012 – August 2012
 - ✓ To develop and validate novel assays for UGT-mediated drug-drug interactions
 - ✓ To characterize CYP7A-mediated metabolism of cholesterol in human liver microsomes
- 4. Graduate Research Assistant, University of Houston**, Houston, TX August 2007 – August 2012
 - ✓ **Thesis project:** Regulation of drug metabolism and hepatotoxicity of prototypical drugs in inflammation.
 - ✓ **Thesis advisor:** Dr. Romi Ghose
- 5. Formulation Intern, Imperial Dax Inc.**, Fairfield, NJ January 2007 - July 2007
 - ✓ Develop new hair care formulations using botanical ingredients
 - ✓ Establish new techniques for effective and stable formulations
 - ✓ Validation of QA and QC reports of daily manufactured batches
- 6. Graduate Assistant, Fairleigh Dickinson University**, Madison, NJ June 2006 - June 2007
 - ✓ Lead projects at The Silberman College of Business on post marketing analysis for food and pharmaceutical industries
- 7. Production Assistant, Q-Max Laboratories Pvt. Ltd.**, Nasik, India December 2004 - December 2005
 - ✓ Learned various techniques used in tablet and capsule manufacturing and testing
 - ✓ Performed QA and QC validation of oral solid dosage forms

TECHNICAL SKILLS

Drug Metabolism skills

- ✓ *In vivo* and *in vitro* pharmacokinetic and pharmacodynamic (PK/PD) studies
- ✓ Hepatocytes and microsomes isolation and preparation for phase I and phase II drug metabolism studies
- ✓ Metabolite identification, fragment assisted structural identification, protein binding assays, and stability assays
- ✓ Analytical techniques: HRMS, LC-MS/MS, TripleTOF, 2D-GC-MS, Solid phase extraction, enzyme hydrolysis, Chemiluminescence, Fluorescence and UV-Vis spectrophotometry

Molecular Biology skills

Immunoblotting	Mouse hepatocyte culture	cDNA synthesis
Real time qPCR	Toxicity assays (ALT/LDH)	DNA/RNA isolation and quantification
Immunostaining	ELISA	Animal handling: I.P./oral injection, blood/organ removal

Computer skills

- ✓ PK modeling software: WinNonlin, NONMEM, and ADAPT II
- ✓ Mass spectrometry softwares: MetabolitePilot, PeakView, LibraryView, Analyst TF, MultiQuant, and Xcalibur
- ✓ Bio-statistical tools: SAS, Minitab and GraphPad Prism
- ✓ Data mining tools: TIBCO Spotfire
- ✓ Chemical structure tools: ChemBioDraw and ChemSketch

Leadership skills

- ✓ President of AAPS-University of Houston Student Chapter October 2009 – November 2010
- ✓ Team oriented with exceptional communication, organizational and public speaking skills.

TEACHING EXPERIENCE

- ✓ Lead Teaching Assistant for Pharmacokinetics and Compounding Pharmacy class of more than 110 Doctor of Pharmacy students for 4 years at the University of Houston
- ✓ Lead Teaching Assistant for Toxicology and Cellular Life Sciences at the University of Houston

INVITED JUDGE

- ✓ Lead Judge in Immunology at The 9th Annual Graduate Research Symposium at NIH January 2013
- ✓ Category Judge at The Montgomery County Science Fair, MD, USA March 2013
- ✓ Primary Judge for Summer Students Poster Competition at NIH August 2013
- ✓ Judge, Chemistry section, 2014 Student Research Showcase for SigmaXi March 2014

EDITORIAL EXPERIENCE

- ✓ Executive Editor, Journal of Clinical Trials, OMICS Group March 2013 – Present
- ✓ Primary Editor, Fellows Editorial Board at the NIH May 2013 – October 2013

HONORS AND AWARDS

- ✓ Graduate student Scholarship at the Fairleigh Dickinson University August 2005 – May 2006
- ✓ AAPS Travel Award for the 2010 Annual Meeting November 2010
- ✓ Yoginder Nath Goel & Swaran Lata Goel Academic Achievement Award – University of Houston October 2011

Peer-review activity

- ✓ Invited Reviewer for *Journal of Pharmacology and Experimental Therapeutics*, *Toxicology In Vitro*, *Toxicological Sciences*, *Archives of Toxicology*, *British Journal of Pharmacology*, *Journal of Clinical Trials*, *Clinical Pharmacology and Therapeutics*, *Chemical Research in Toxicology*, and *Journal of the American Society for Mass Spectrometry*.
- ✓ Abstract Reviewer for the 2013 Annual AAPS-National Biotechnology Conference
- ✓ Abstract Reviewer for the 2014 Annual AAPS-National Biotechnology Conference
- ✓ Abstract Reviewer for the 2014 Annual AAPS-National Conference

PROFESSIONAL MEMBERSHIPS

- ✓ American Association of Pharmaceutical Scientists (AAPS) August 2007 – Present
- ✓ American Society of Pharmacology and Experimental Therapeutics (ASPET) March 2011 – Present
- ✓ American Association for the Study of Liver Diseases (AASLD) September 2011 – Present
- ✓ International Society for the Study of Xenobiotics (ISSX) May 2013 – Present
- ✓ Sigma Xi May 2014 – Present

Publications

- ✓ **Gandhi A**, Guo T and Ghose R (2010) Role of c-Jun N-terminal kinase (JNK) in regulating tumor necrosis factor- α (TNF- α) mediated increase of acetaminophen (APAP) and chlorpromazine (CPZ) toxicity in murine hepatocytes. *Journal of Toxicological Sciences*. 35: 163-173.
- ✓ Ghose R, Guo T, Vallejo JG and **Gandhi A** (2011) Differential Role of Toll-Interleukin 1 Receptor Domain-Containing Adaptor Protein in Toll-like receptor 2-Mediated Regulation of Gene Expression of Hepatic Cytokines and Drug Metabolizing Enzymes. *Drug Metabolism and Disposition*. 39: 874-881.
- ✓ Ghose R, Omoluabi O, **Gandhi A**, Shah P, Strohacker K, Carpenter K.C, McFarlin B and Guo T (2011) Role of high-fat diet in regulation of gene expression of drug metabolizing enzymes and transporters. *Life Sciences*. 89: 57-64.
- ✓ **Gandhi A**, Shah P, Guo T, Moorthy B, Chow S-L, D, Hu M and Ghose R (2012) CYP3A-dependent drug metabolism is reduced in bacterial inflammation in mice. *British Journal of Pharmacology*. 166: 2176-2187
- ✓ **Gandhi A**, Moorthy B and Ghose R (2012) Drug Disposition in Pathophysiological Conditions. *Current Drug Metabolism*. 13: 1327-44
- ✓ **Gandhi A**, Guo T, Moorthy B and Ghose R (2012) Chlorpromazine-induced hepatotoxicity in inflammation is mediated by TIRAP-dependent signaling pathway in mice. *Toxicology and Applied Pharmacology*. 266: 430-438
- ✓ **Gandhi A**, Zhu M, Pang S, Wohlfarth A, Scheidweiler KB, Liu HF, Huestis MA (2013) First Characterization of AKB-48 Metabolism, a Novel Synthetic Cannabinoid, Using Human Hepatocytes and High-Resolution Mass Spectrometry. *The AAPS Journal*. 15: 1091-8
- ✓ Wohlfarth A, Pang S, Zhu M, **Gandhi A**, Scheidweiler KB, Liu HF, and Huestis MA (2013) First metabolic profile of XLR-11, a novel synthetic cannabinoid, using human hepatocytes and high-resolution mass spectrometry. *Clinical Chemistry*. 59: 1638-48
- ✓ Wohlfarth A, **Gandhi A**, Pang S, Zhu M, Scheidweiler KB, and Huestis MA (2013) Metabolism of Synthetic Cannabinoids PB-22 and its 5-Fluoro Analog, 5F-PB-22, by Human Hepatocyte Incubation and High-Resolution Mass Spectrometry. *Analytical and Bioanalytical Chemistry*. 406: 1763-80
- ✓ **Gandhi A**, Zhu M, Pang S, Wohlfarth A, Scheidweiler KB, Liu HF, Huestis MA (2014) Metabolite Profiling of RCS-4, a Novel Synthetic Cannabinoid Designer Drug, using Human Hepatocyte Metabolism and Time of Flight Mass Spectrometry. *Bioanalysis*. 6: 1471-85
- ✓ Wohlfarth A, Pang S, Zhu M, **Gandhi A**, Scheidweiler KB, Liu HF, and Huestis MA (2014) Rapid Metabolite Detection and Structural Characterization of RCS-8, a Phenylacetylindole Synthetic Cannabinoid with Cyclohexyl Substructure, in Human Hepatocytes by High-Resolution Mass Spectrometry. *Bioanalysis*. 6: 1187-200
- ✓ **Gandhi A**, Wohlfarth A, Zhu M, Pang S, Castaneto M, Scheidweiler KB, and Huestis MA (2014) High-resolution mass spectrometric metabolite profiling of a novel synthetic designer drug, N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indole-3-carboxamide (STS-135) using cryopreserved human hepatocytes and assessment of metabolic stability with human liver microsomes. *Drug Testing and Analysis* (DOI: 10.1002/dta.1662)
- ✓ Castaneto MS, Scheidweiler KB, **Gandhi A**, Wohlfarth A, Klette KL, Martin TM and Huestis MA (2014) Quantitative urine confirmatory testing for synthetic cannabinoids in randomly collected urine specimens. *Drug Testing and Analysis* (DOI: 10.1002/dta.1709)
- ✓ Wohlfarth A, Scheidweiler KB, Castaneto M, **Gandhi A**, Desrosiers NA, Klette KL, Martin TM and Huestis MA (2014) Urinary prevalence, metabolite detection rates, temporal patterns and evaluation of suitable LC-MS/MS targets to document synthetic cannabinoid intake in US military urine specimens. *Clinical Chemistry and Laboratory Medicine* (DOI: 10.1515/cclm-2014-0612)

Manuscripts under preparation

- ✓ **Gandhi A**, Gorelick D and Huestis MA (2014) Therapeutic potential of cannabinoids – From bench to bedside
- ✓ Poda SB, Norinder U, Budac DP, **Gandhi A**, Menon V, Broadbeck R, Li G, Campbell B, and Kobayashi M (2014) Development of Surface Plasmon Resonance Assay for Characterization of Small Molecule Binding Kinetics to Kynurenine 3-Monooxygenase
- ✓ Shah P, **Gandhi A**, Guo T and Ghose R (2014) Altered Irinotecan Pharmacokinetics in Diet-Induced Obese (DIO) mice

Book Chapter

- ✓ **Adarsh Gandhi** and Romi Ghose (2012). Altered Drug Metabolism and Transport in Pathophysiological Conditions, Topics on Drug Metabolism, James Paxton (Ed.), ISBN: 978-953-51-0099-7, InTech. Available from: <http://www.intechopen.com/articles/show/title/altered-drug-metabolism-and-transport-in-pathophysiological-conditions>

Podium Presentations

- ✓ **Adarsh Gandhi**, Tao Guo and Romi Ghose. Inflammation-induced hepatotoxicity of chlorpromazine is mediated by the Toll-interleukin 1 receptor adaptor protein (TIRAP) Gulf Coast Society of Toxicology (GCSOT 2010); Houston, TX
- ✓ **Adarsh Gandhi**, Tao Guo, Ming Hu, Pranav Shah and Romi Ghose. Metabolism of midazolam is compromised in inflammation. Experimental Biology (EB 2011); Washington DC
- ✓ Ariane Wohlfarth, **Adarsh Gandhi**, Karl B. Scheidweiler, Marisol S. Castaneto, Nathalie A. Desrosiers, Eliani Spinelli, Sheena Young, Allan J. Barnes and Marilyn A. Huestis. Automated and semi-automated screening, LCMSMS confirmation and human hepatocyte high-resolution metabolism studies of synthetic cannabinoids. 20th International Conference on Alcohol, Drugs and Traffic Safety (T2013), Brisbane, Australia

Peer-reviewed Abstracts

- ✓ **Adarsh Gandhi** and Minal Harde, Determination of anti-fungal activity of *Rubia cordifolia* and *Trigonella foenum-graecum* against dermatophytes using cell culture and inoculation technique (May 2005); NDMVP's College of Pharmacy, India
- ✓ Romi Ghose, Tao Guo, Nadia Haque and **Adarsh Gandhi**. Role of Toll-like receptor 2 signaling pathway in regulating the gene expression of hepatic drug metabolizing enzymes. Gordon research Conference on Drug Metabolism (July 2008); Holderness, NH
- ✓ **Adarsh Gandhi**, Tao Guo and Romi Ghose. Regulation of drug hepatotoxicity in inflammation. The 22nd Annual meeting of the American Association of Pharmaceutical Scientists (AAPS 2008); Atlanta, GA
- ✓ **Adarsh Gandhi**, Tao Guo, Gaurav Dhar and Romi Ghose. Role of cytokines in regulating drug-induced hepatotoxicity. Frontiers in Digestive Diseases Symposium (February 2009); Houston, TX
- ✓ Ghose, R, T. Guo, **Adarsh Gandhi**, S.J. Karpen and D. White. Role of Toll-like receptors on hepatocytes in regulating the gene expression of drug metabolizing enzymes. The 59th Annual meeting of the American Association for the Study of Liver Diseases (AASLD 2008); San Francisco, CA
- ✓ **Adarsh Gandhi**, Tao Guo and Romi Ghose. Toll-like receptors: Novel regulators of hepatic drug metabolism. The 60th Annual meeting of the American Association for the Study of Liver Diseases (AASLD 2009); Boston, MA
- ✓ **Adarsh Gandhi**, Tao Guo and Romi Ghose. Midazolam metabolism is compromised in Inflammation. 16th International conference of Inflammation Research Association (IRA 2010); Chantilly, VA
- ✓ **Adarsh Gandhi**, Tao Guo, Ming Hu and Romi Ghose. Inflammation-induced hepatotoxicity of chlorpromazine is mediated by the Toll-interleukin 1 receptor adaptor protein (TIRAP). Annual conference of Gulf Coast Chapter Society of Toxicology (GCSOT 2010); Houston, TX
- ✓ **Adarsh Gandhi**, Tao Guo and Romi Ghose. Role of Toll-interleukin 1 receptor domain containing adaptor protein (TIRAP) and c-Jun-N-terminal kinase (JNK) in hepatotoxicity of chlorpromazine. The 24th Annual meeting of the American Association of Pharmaceutical Scientists (AAPS 2010); New Orleans, LA
- ✓ **Adarsh Gandhi**, Tao Guo, Pranav Shah and Romi Ghose. Metabolism of midazolam is compromised in inflammation. Experimental Biology (EB 2011); Washington DC
- ✓ **Adarsh Gandhi**, Tao Guo, Pranav Shah and Romi Ghose. Toll-like receptor signaling adaptor protein, TIRAP, regulates the hepatotoxic responses of chlorpromazine in inflammation. The 62nd Annual meeting of the American Association for the Study of Liver Diseases (AASLD 2011); San Francisco, CA
- ✓ **Adarsh Gandhi**, Pranav Shah and Romi Ghose. Altered metabolism of irinotecan (CPT-11) in diet-induced obese mice. Annual Conference of Texas Screening Alliance for Cancer Therapeutics (TxSACT 2012); Houston, TX
- ✓ Pranav Shah, **Adarsh Gandhi**, and Romi Ghose. Altered Irinotecan Pharmacokinetics in Diet-Induced Obesity. Texas Obesity Research Center Conference (TORC 2012); Houston, TX
- ✓ Ariane Wohlfarth, **Adarsh Gandhi**, Shaokun Pang, Mingshe Zhu, Hua-fen Liu and Marilyn A. Huestis. Rapid generation of synthetic cannabinoids' "metabolite fingerprints" following human hepatocyte metabolism and high resolution mass spectrometry. The 61st Annual meeting of the American Society for Mass Spectrometry (ASMS 2013); Minneapolis, MN
- ✓ **Adarsh Gandhi**, Ariane Wohlfarth, Shaokun Pang, Mingshe Zhu, Hua-fen Liu and Marilyn A. Huestis. Metabolite

detection and structural characterization of AKB-48, a novel synthetic cannabinoid, following human hepatocyte metabolism and high resolution mass spectrometry (HRMS). The IRB-PI Clinical Retreat at the National Institute on Drug Abuse (NIDA) (March 2013); Baltimore, MD

- ✓ **Adarsh Gandhi**, Mingshe Zhu, Shaokun Pang, Ariane Wohlfarth, Karl B. Scheidweiler, Hua-fen Liu and Marilyn A. Huestis. Identification of Metabolites of AKB-48, a Novel Synthetic Cannabinoid, using Human Hepatocytes and High Resolution Mass Spectrometry. Society of Forensic Toxicologists (SOFT 2013); Orlando, FL
- ✓ Pranav Shah, **Adarsh Gandhi** and Romi Ghose. Altered Irinotecan Pharmacokinetics in Diet-Induced Obesity. Society of Toxicology (SOT 2013); San Antonio, TX.
- ✓ Karl B. Scheidweiler, Ariane Wohlfarth, **Adarsh Gandhi**, Xiang He, Xiaohong Chen, Hua-fen Liu, and Marilyn A. Huestis. Development and Evaluation of a High-throughput Screening Method for Synthetic Cannabinoids/ Metabolites in Urine with Q-TOF Mass Spectrometer and Multiplexed LCs. Society of Forensic Toxicologists (SOFT 2013); Orlando, FL
- ✓ Pranav Shah, **Adarsh Gandhi** and Romi Ghose. Altered Irinotecan Pharmacokinetics and Toxicity in Diet-Induced Obesity. American Association of Pharmaceutical sciences (AAPS 2013); San Antonio, TX.
- ✓ **Adarsh Gandhi**, Mingshe Zhu, Shaokun Pang, Ariane Wohlfarth, Karl B. Scheidweiler, and Marilyn A. Huestis. Characterizing the Novel Synthetic Cannabinoid, RCS-4's Metabolism – Human Hepatocytes Applicability in Clinical and Forensic Drug Testing. The 62nd Annual meeting of the American Society for Mass Spectrometry (ASMS 2014); Baltimore, MD
- ✓ **Adarsh Gandhi**, Manuel Cajina, Megan Nattini, Megan McAleavy and Gamini Chandrasena. An ex vivo Equilibrium Dialysis (ED) assay for measuring *in vivo* brain and plasma drug free fraction. The 19th Annual meeting of the International Society for the Study of Xenobiotics (ISSX 2014); San Francisco, CA

REFERENCES

- ✓ Dr. Diana Chow, Professor, Department of Pharmacological and Pharmaceutical Sciences, University of Houston. (E) dchow@uh.edu (P) 713-795-8308
- ✓ Dr. Bhagavatula Moorthy, Professor, Department of Pediatrics – Neonatology, Baylor College of Medicine. (E) bmoorthy@bcm.edu (P) 832-824-3266
- ✓ Dr. Romi Ghose, Assistant Professor, Department of Pharmacological and Pharmaceutical Sciences, University of Houston. (E) rghose@uh.edu (P) 713-795-8343
- ✓ Dr. Gamini Chandrasena, Director Bioanalysis and Physiology, Lundbeck Research USA Inc. (E) gch@lundbeck.com (P) 201-350-0539